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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,765	01/14/2004	Per Egnelov	030481-0212	1510

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FOLEY AND LARDNER LLP
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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/756,765

Applicant(s)

EGNELOV ET AL.

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-16 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,11,15 and 20 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10,14 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This is final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 14, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,246,426 to Lewis et al. Lewis teaches an indicator device comprising a body 22, 74, 92 comprising a passage 42 passing through the body 22, 74, 92, the body 22, 74, 92 further comprising a duct 82, 108 extending in the body and having a hemostatically sealed blood accommodating chamber 38, 40 (see entire document, especially figs. 1-6D, 7, and 8B; col. 4, lines 27-48; col. 5, lines 8-42; col. 7, lines 14-49; col. 9, line 15-34 of Lewis). An insertion tube 14, 70 comprises a distal end portion 14b, 70b adapted to be positioned inside the blood vessel and comprising a fluid communication pathway between an liquid inlet opening 70d near a distal end of the insertion tube and the duct. The insertion tube further comprises an opening at the extreme end of the distal end portion (see entire document, especially Figs. 1, 6C, 7, and 8B; col. 4, lines 33-39; col. 5, line 65-col. 6, line 2; col. 6, line 56-col. 7, line 13; col. 7, lines 27-34; col. 9, line 16-34 of Lewis). A window 24, 26, 92, 106 comprises an at

least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (see entire document, especially figs. 4, 5, 6B & C, 7; col. 5, lines 14-23; col. 8, lines 17-27; col. 10, lines 25-30 of Lewis). An elongated member 16 is further included (figs. 1, 6A, 8B of Lewis). The passage and fluid communication pathway are adapted to permit the elongated member to be threaded in a substantially straight path there through between a distal end of the insertion tube and a proximal end of the body (see entire document, especially figs. 1, 3, and 8B of Lewis). The liquid inlet opening near the distal end of the insertion tube may be uncovered, in that the insertion tube 14, 70 may be removed from the catheter body 192 (see entire document, especially col. 4, lines 49-53; fig. 6c of Lewis).

As to the limitation "for visually indicating a pressure of blood inside a blood vessel", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Lewis teaches all of the claimed structural limitations and their recited relationships. The system of Lewis is certainly capable of being used to visually indicate a pressure of blood inside a blood vessel.

Regarding claim 3, the duct opens into the chamber via an aperture 84, 86 having a spill-over edge 78, the aperture being located at a level above a bottom surface of the blood accommodating chamber 38, 40, whereby return of flow of blood back into the duct is prevented (see entire document, especially figs. 4, 6B & C of Lewis).

Regarding claim 4, the blood accommodating chamber 38, 40 is located in the body 22, 74, and the body further comprises the insertion tube 14, 70 extending distally of the body (see entire document, especially figs. 1 & 4 of Lewis).

Regarding claim 5, the inlet 70d is located on a side of the insertion tube (see entire document, especially fig. 6C & 8B of Lewis).

Regarding claims 6 and 7, the duct extends vertically or horizontally to an aperture 84, 86 opening into the blood accommodating chamber 38, 40 (see entire document, especially figs. 4, 6B & C of Lewis), wherein the direction of the duct's extension (vertically or horizontally) is merely "intended use" language since it depends on how the device is held. The device of Lewis may be held such that the duct extends vertically or horizontally. In a horizontal position, a portion of the duct 82 extends above a portion 40 of the blood-accommodating chamber to an aperture 86 into the chamber (see entire document, especially figs. 4, 6B & C of Lewis).

Regarding claim 8, the duct 82, 108 exhibits a varying cross-section over its length (see entire document, especially figs. 7, 8A, 8B of Lewis).

Regarding claims 10 and 14, the elongated member 16 may be threaded in a substantially straight path through the passage and fluid communication pathway such that the elongated member projects distally past the extreme end of the distal end portion (see entire document, especially figs. 1 & 8B; col. 5, line 61-col. 6, line 2 of Lewis).

Regarding claims 21-23, the elongated member 16 wherein the elongated member 16 is considered to be a guide wire, guide rod, or dilator (see entire document,

especially col. 4, line 32 of Lewis; also see col. 10, lines 17-38 and figures 3 and 8 of US Patent No. 6,689,070 to Hung which shows a dilator 40 being an elongated member used to advance a catheter into a body opening and similar to the guide wire of Lewis).

Response to Arguments

Applicant's arguments filed 9/29/06 have been fully considered but they are not persuasive.

The applicants state that the claims have been amended to further distinguish over Lewis in that the port 70d is covered rather than "uncovered" as claimed. However, as stated in the rejection above, the insertion tube 14, 70 is removable from the catheter 92, and therefore the port 70d may be uncovered, as claimed. Therefore, the claims remain rejected as being anticipated by Lewis.

Allowable Subject Matter

Claims 9, 11, 15, and 20 are allowed. The allowability of claims 9 and 15 were addressed in a previous Office action filed 4/20/05. The allowability of claims 11 and 20 were addressed in a previous Office action filed 6/30/06.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The allowability of claim 16 was addressed in a previous Office action filed 6/30/06.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

for
pcm


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